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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/705,457	11/02/00	ANDYA J	P0998D3

HM12/1019

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EXAMINER	
JAMROZ, M	
ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/705,457	Applicant(s) ANDYA ET AL.	
	Examiner Margaret E Jamroz	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2000 and 08 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-44* is/are pending in the application.

4a) Of the above claim(s) *41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-40 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☒ Other: *3 references* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology Center 1600.

2. Applicant's amendment filed November 2, 2000 (Paper No. 2) and Applicant's response filed August 8, 2001 (Paper No. 6) are acknowledged and have been entered.

Claims 1-36 have been canceled.
Claims 37-44 have been added.
Claims 41-43 have been withdrawn from consideration.
Claims 37-40 and 44 are pending.

3. Applicant's election of Group I (claims 37-40 and 44) in Paper No. 6 is acknowledged.

Claims 37-40 and 44 are currently being examined as they read on a method for treating an IgE-mediated disease in a mammal comprising administering a formulation comprising an antibody which binds IgE.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 41, 42, and 43 (non-elected groups II-IV) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

4. Applicant's petition to correct inventorship under 37 CFR 1.48(b) filed on November 2, 2000, is acknowledged and Jeffrey L. Cleland, Xanthe M. Lam, David E. Overcashier, and Janet Yu-Feng Yang have been removed.

The inventors of the instant application are James Andya, Chung C. Hsu, Steven J. Shire, and Sylvia Sau-Yan Wu.

IDS

5. Applicant's reliance on parent applications for references cited on the IDS is acknowledged, however, the references for the citations crossed out were not found in the priority documents. Applicant is invited to produce such documents. The examiner apologizes for any inconvenience to applicant in this matter.

Title

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Abstract

7. The abstract of the disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

Complete revision of the contents of the abstract is required on a separate sheet.

Drawings

8. The formal drawings submitted November 2, 2000, have been approved by the Draftsman.

Informalities

9. The disclosure is objected to because of the following informalities:

The use of the trademark "MILLI-Q" on page 37 at line 19 has been noted in this application. It should be capitalized or accompanied by the ™ or ® symbol wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Priority

10. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 35 U.S.C. 120 and/or 121 is acknowledged. However, the provisional USSN 60/029,182 was not available to the examiner at this time. Therefore, the examiner could not determine whether the instant claims have priority to said application.

The filing date of the instant claims is deemed to be the filing date of parent application USSN 08/615,369, i.e. 3/14/1996.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 37-40 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed.

This is a New Matter rejection for the following reasons:

The amendatory material that is not supported in the specification and claims as originally filed is: "of about 50 mg/mL to about 400 mg/mL".

Applicant's amendment filed November 2, 2000, pointed to canceled claims 8, 9, and 27, and to page 25, lines 17-18 in the instant specification to support the instant claims (Paper No: 1).

The specification as filed does not provide an adequate written description of the phrase "of about 50 mg/mL to about 400 mg/mL". The specification does not provide sufficient blazemarks nor direction for the above-mentioned "of about" range as it is currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action.
Alternatively, applicant is invited to clearly point out the written support for the instant limitations.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. Claims 37-40 and 44 rejected under 35 U.S.C. 102(e) as being anticipated by Presta et al., U.S. Patent No. 5,965,709 (see entire document).

Presta et al. teach allergy therapy using an anti-IgE antibody or other anti-IgE fragments such as Fab, Fab', and the like (see column 32, paragraph 3), including modes of administration such as subcutaneous injection (see column 33, paragraph 1), dosages such as about 2 to 3 mg/kg for the treatment of acute allergic symptoms (IgE-mediated diseases) encompassed by the claimed methods (See column 33, paragraph 4). In addition, Presta et al. teach pharmaceutical grade excipients, such as mannitol, lactose, starch, magnesium carbonate, magnesium stearate, sodium saccharin, and cellulose which would serve as lypoprotectants, encompassed by the claimed invention (See column 33, paragraph 1).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the reference methods to treat allegies with anti-IgE antibodies.

The patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113.

Therefore, the claimed recitation of preparing and reconstituting the anti-IgE antibody in the claimed methods is met by the administration of therapeutic effective amounts of about 2-3 mg/kg of anti-IgE antibody in the treatment of allergic diseases as taught by the prior art reference.

In addition, applicant is reminded that "[W]hen, as by recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original); and see the concurring opinion in Ex parte Lee, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993). See MPEP 2131.03.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 37-40 and 44 rejected under 35 U.S.C. 103(a) as being unpatentable over Presta et al. (U.S. Patent No. 5,965,709) in view of Ultee et al. (U.S. Patent No. 5,942,210) AND/OR Ressing et al. (Pharmaceutical Research (1992). 9 (2): 266-270).

Presta et al. taught above supra. See the entire document.

Presta et al. differs from the instant application by not teaching all of the disclosed lypoprotectants disclosed in the instant specification (e.g. see page 12, paragraphs 2 and 3) for the anti-IgE antibody and by not teaching the stability of lyophilization on an antibody. See the entire document.

Ultee et al. teach sugars, e.g., mannitol, sucrose, and trehalose, can be used as lypoprotectants for molecules such as therapeutic antibodies. See the entire document, including column 4, paragraph 1; and column 2, paragraph 2.

Ressing et al. teach that a adding a lypoprotectant to a monoclonal antibody does not affect the lyophilization process, however, the addition of sucrose, dextran, or HPβCD dramatically increased antibody stability during storage. Antibodies lyophilized with a lypoprotectant also retained about 70% of the antibody's activity compared to the antibody lyophilized alone. See the entire document, including page 267, column 2, paragraph 4 and page 268, column 1, paragraph 4.

Given the teachings of the allergy therapy using an anti-IgE antibody or other anti-IgE fragments such as Fab, Fab', and the like in Presta et al., the ordinary artisan would have been motivated to substitute a mannitol, trehalose, sucrose, dextran or HPβCD as lypoprotectants taught in Ultee et al. and Ressing et al. in conjunction with a an antibody to increase the stability of the lyophilized formulation and to preserve the activity of the antibody for the treatment of IgE-mediated diseases.

A person of ordinary skill in the art at the time the invention was made would have recognized that the claimed limitations discussed by both secondary references would be suitable equivalents of pharmaceutical compositions, such as an anti-IgE antibody, with the limitation of the primary reference. Therefore, a person of ordinary skill in the art would have a reasonable expectation of success at the time the invention was made. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable matter

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Patent Examiner
Technology Center 1600
October 16, 2001

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